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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,684	05/04/2006	Andreas Hefel	RBL0109-01	7978

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EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,684	HEFEL, ANDREAS	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,28 and 31-44* is/are pending in the application.

4a) Of the above claim(s) *23,24,28 and 31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/2010 has been entered.

Applicant's amendment in the reply filed on 3/29/2010 is acknowledged, with the cancellation of Claims 1-21, 25-27, 29-30. Claims 22-24, 28, and 31-44 are pending. Claims 23, 24, 28, and 31-43 are withdrawn from further consideration. **Claims 22 and 44 are examined on the merits**.

The amended claims filed by Applicant have very small font and faint color. Please write claims with font size of at least 12, and make claims readable.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites "providing a somatotropin human growth hormone embedded in a galactomannan and/or a glucomannan; at least one nutritional additive selected from the group consisting of herbal extracts, water-soluble vitamins, fat-soluble vitamins, amino acids, fatty acids, minerals and hormones; and at least one antioxidant selected from the group consisting of mixed carotenoids, co-enzymes Q10, lycopenes, lutein, zeaxanthin, bioflavonoids, germanium, selenium, zinc, vitamin A, vitamin C, vitamin E, alpha-lipoic, grape sperm phytosome, extract from green tea and extract from pine bark" (lines 5-14).

First of all, somatrotropin, nutritional additive and antioxidant recited by Applicant overlap in concepts. For instance, somatotropin is a hormone, thus it is a nutritional additive, and it does not require an additional nutritional additive in order to meet the limitation of "at least one nutritional additive". Secondly, vitamin A and vitamin E are fat-soluble vitamins; and vitamin C is water-soluble vitamin, thus nutritional additive overlaps in concept with antioxidative. Furthermore, it is not clear what Applicant means by "grape sperm phytosome" (line 13).

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 22 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (WO 97/26865), in view of Kim et al (KR 143767 B1).

Baichwal teaches a sustained-release formulation (thus increase of the nutrient-bio-availability of vital substances in a human or an animal) for use in oral solid dosage forms includes from about 10 to about 40 percent or more by weight galactomannan gum; from about 1 to about 20 percent by weight of an ionizable gel strength enhancing agent and an inert pharmaceutical filter (see Abstract). Baichwal also teaches in certain preferred embodiments for the invention, the sustained release matrix further comprises a hydrophobic material in an amount effective to slow the hydration of the gum without disrupting the hydrophilic matrix formed by the homolysaccharide when the formulation is exposed to fluids in an environment of use. This may be accomplished by granulating the sustained release matrix prior to the incorporation for the medicament (thus are embedded in a botanical matrix of a botanical matrix of a polysaccharide). The hydrophobic material may be selected from alkylcelluloses, acrylic and/or methacrylic acid polymers or copolymers, hydrophobic vegetable oils (thus herbal extracts; thus at least one nutritional additive), zein, as well as other pharmaceutically acceptable hydrophobic materials known to those skilled in the art (page 9, lines 9-22). Baichwal also teaches the homopolysaccharide gums used in the present invention include the galactomannan,

i.e. polysaccharides which are composed solely of mannose and glactose. Galactomannans which have higher proportions of unsubstituted mannose are preferred in certain embodiments. Locust bean gum, which has a higher ratio of mannose to the galactose, is especially preferred as compared to other galactomannans such as guar and hydroxyproply guar (page 6, lines 13-18) (thus are embedded in a botanical matrix of a botanical matrix of a polysaccharide). Baichwal further teaches accordingly, the ingredients of the sustained release pharmaceutical excipient prepared in accordance with the present invention may be subjected to wet granulation before the medicament is added (thus somatotropin, the nutritional additive and the antioxidant in the granulate do that interact with one another; thus the granulate swells in a digest system of a human or an animal slowly releasing a nutritiously active quantity of said somatotropin, the nutritional additive, and the antioxidant for absorption by the human or animal digestive system). In this technique, the desired amounts of the homopolysaccharide, the ionizable gel strength enhancing agent, and the inert filler are mixed together and thereafter a moistening agent such as water, propylene glycol, glycerol, alcohol or the like is added to prepare a moistened mass. Next, the moistened mass is dried. The dried mass is then milled with conventional equipment product is ready to use. The granulate thus obtained has certain advantages including the fact that it is free-flowing, has good cohensive properties, and can be admixed with an active agent (e.g., drug) (thus somatotropin, the nutritional additive and the antioxidant in the granulate do that interact with one another) and can be directly compressed into tablets (page 11, lines 7-23). Baichwal teaches alternatively, the medicament may be wet-granulated in appropriate circumstance with one or more of the ingredients of the sustained release excipient. The remaining release excipient ingredients can simply be admixed to the resultant pre-granulated

material or granulated together with the pre-granulated ingredients (thus somatotropin, the nutritional additive and the antioxidant in the granulate do that interact with one another) in a second wet granulation step (page 12, lines 3-9) (thus the granulates swells in a digest system of a human or an animal slowly releasing a nutritiously active quantity of said somatotropin, the nutritional additive and the antioxidant for absorption by the human or animal digestive system). Baichwal further teaches finally, in further alternative embodiments of the invention, a therapeutically active agent can be incorporated (admixed, granulated, etc.) with any of the ingredients of the sustained release excepient, if so desired (page 13, lines 24-30). Baichwal at last teaches examples of such therapeutically active agents include hormones (e.g., insulin, heparin), vitamins etc (thus at least one antioxidant) (page 16, last paragraph bridging page 17).

Baichwal does not teach explicitly somatotropin is embedded in galactomannan and/or glucomannan.

Kim et al teach an implantable formula containing somatotropin is provided for sustained release of somatotropin that promotes animal's growth. A process for the preparation of sustained releasing formula containing somatotropin comprises of: mixing polyethylene glycol, the water-soluble polymer with somatotropin or liposome bovine somatotropin; adding some water and mixing; granulation; coating granulated compd. by spraying hydroxyl Pr cellulose dissolved in ethanol using spray gun; making tablet or pellet by tablet machine (see Abstract, machine translation is attached).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to embed somatotropin human growth hormone in a galactomannan and/or a glucomannan since Baichwal teaches embedding therapeutically active agents such as hormones

in sustained-release granulate containing galactomannan gum; Kim et al teach somatotropin in a sustained-release granulate; therefore, one of the ordinary skills in the art would have been motivated to embed somatotropin human growth hormone in a galactomannan and/or a glucomannan. Since both of the references teach granulation of sustain release hormone, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 22 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal and Kim et al as applied to claim 22 above, and further in view of Shefer et al (US 2003/0195133).

The teachings of Baichwal and Kim et al are set forth above and applied as before.

The combination of Baichwal and Kim et al does not specifically teach the nutritional material comprises antioxidant coenzyme Q10.

Shefer et al teach controlled delivery composition (see Title). Shefer et al teach the controlled release system of the invention can also contain other antioxidants including those well known in the art. Representative antioxidants include vitamin E, tocopheryl acetate, betaglucan, and coenzyme Q10 [0136].

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adopt the procedure of using antioxidant coenzyme Q10, or vitamin E in the slowly released/control released system since Shefer et al teach the controlled release system of the invention can also contain antioxidants coenzyme Q10 or vitamin E. Furthermore, since Baichwal teaches galactomannan and/or a glucomannan allowing sustainment of pharmacological effect of a variety of active ingredients administered to mammals, one of ordinary skill in the art would have adopted the procedure of using glucomannan to sustain the pharmacological effect of antioxidant coenzyme Q10, or vitamin E.

Since all the references yielded beneficial results in sustained release system, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments, regarding the cited references do not teach the new claim limitation "granulation", have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Baichwal and Kim et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655